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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/853,544 | 05/10/2001 | Miguel S. Barbosa | 10624-051 | 7460 |
| 20583 | 7590 | 08/31/2005 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | PAK, MICHAEL D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,544

Applicant(s)

BARBOSA ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 26-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

5.00

DETAILED ACTION

Response to Amendment

1. The amendment filed 2 February 2005 has been entered. Claims 1-12 and 17-25 have been cancelled. Claims 13-16 and 26-27 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 2 February 2005, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

4. Claims 13, 15-16 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that a specification that discloses the specific nucleotide sequence which satisfies the written description requirement. However, essential feature of the claimed method is the discovery that nucleic acid sequences which have not been identified by function (i.e. orphan proteins) such as SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is

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not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. Orphan proteins whose function is not known. Thus, the disclosure of an orphan nucleic sequence is not sufficient disclosure where the function of the protein or nucleic acid is known.

Applicants argue that the specification describes several species to provide description for a genus and therefore meets the standard established for adequate written description of sequences by the Federal Circuit. However, essential feature of the claimed method is the discovery of nucleic acid sequences which have not been identified by function such SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. There is lack of written description for a method for genus of nucleic acid whose function is not known. The ability to regulate the nucleic acid does not provide sufficient written description for the nucleic acid whose function is not known.

5. Claims 13-16 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a a method of using estrogen

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receptor marker with function, does not reasonably provide the full scope of enablement for a method of using an estrogen receptor marker which is an orphan protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims encompass using a method using estrogen receptor marker which are orphan proteins. However, the specification does not teach how to use any peptide fragments, substantial equivalents, or modified peptide derivatives fragments of estrogen receptor marker which are not functional. Proteins have a functional domain which require specific folding. A fragment of the protein which is truncated in the middle of the domain or a fragment which does not allow the proper folding of the hydrophobic pocket would not be expected to function since the protein could not interact with the pocket necessary for intracellular function. The state of the art is such that one skilled in the art cannot predict the outcome of changes to protein structure using the primary amino acid structure as the predictor^u(~~o~~). Thus, one skilled in the art cannot use the primary amino acid sequence of SEQ ID NO: polypeptide alone to predict the tertiary structure of SEQ ID NO:26 polypeptide which would be required to determine function and proper folding of polypeptide. No working example is provided to determine whether a change in the folding of the polypeptide fragment or variant which can function. No known function is provided in the specification for the orphan protein. Furthermore, without a function, it would require empirical experimentation to determine the function of the orphan protein. Thus, such fragments encompass a genus with a

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large number of species which are not functional. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

Claim Rejections - 35 USC § 102

6. Claims 13,15-17 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendelsohn et al.(US 5,728,534).

The reason for the rejection has been set forth in the previous office actions.

Newly submitted claims 27 limitation to "different assays" is taught by Mendelsohn et al. (columns 2-11).

Applicants argue that Mendelsohn does not teach the method of identifying selective estrogen receptor modulators using at least one endogenously-expressed ERM in the cells. However, the claims are not limited to endogenously-expressed ERM in the cells because no such claim limitations are in the claims.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Pak
Primary Patent Examiner
Art Unit 1646
26 October 2004